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| 09/879,433 | 06/12/2001 | Robert J. Crowley | BSC-009DV | 4101 |

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EXAMINER

SHAY, DAVID M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 04/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,433

Applicant(s)

Crowley

Examiner

d. Shay

Group Art Unit

3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE —3— MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on January 13, 2003
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 14-40 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 14-40 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14-18, 21-25, 27, 28, 33-37, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke in combination with Selman et al. Clarke teaches a method as claimed except for the use on the particular surface tissue and on the esophagus, throat, intestine, colon, bladder, using a dye or drug, redirecting the light, and filtering the light. Selman et al teach the method as claimed except the use of a flash lamp per se. It would have been obvious to employ the light source of Clarke in the method of Selman et al, since Selman et al teach that any of a variety of light sources can be used, alternatively it would have been obvious to employ the method of Clarke in the various organs claimed and with the various filtering, dying, redirecting steps, and structure since these help enhance the efficaciousness of the method and help identify tissue to be treated, as taught by Selman et al, thus producing a method such as claimed.

Claims 14, 19, and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke in combination with Anderson et al. Clarke teaches a method such as claimed except the particular surface tissue and performing the method on the uterus. Anderson et al teach the desirability of using light to ablate the endometrium, but does not teach the use of a flashlamp, per se. It would have been obvious to the artisan of ordinary skill to employ the method of Clark to ablate the endometrium, since this is one of the tissues that responds to light ablation, as taught by Anderson et al, alternatively it would have been obvious to the artisan of ordinary skill to employ a flashlamp as the light source in the method of Anderson et al, since these are equivalent to lasers, as taught by Clarke thus producing a method such as claimed.

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Claims 14-18, 20-25, 27-29, 33-37, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke in combination with Selman et al as applied to claim 14 above, and further in view of Waksman et al. Waksman et al teach the use of a balloon to surround the treatment device and the applicability of treatments of blood vessel and bladder surfaces to the surface of the urethra. Thus it would have been obvious to the artisan of ordinary skill to employ the combined method of Clarke and Selman et al on any of the tissues of Waksman et al, since these are equivalents; and to employ a balloon on the device, since this would help center the device during treatment, thus producing a method such as claimed.

Claims 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke in combination with Selman et al and Waksman et al as applied to claims 14-18, 20-25, 27-29, 33-37, 39 and 40 is above, and further in view of Spears. Spears teaches a method such as claimed except the use of a lenticular element and a flashlamp per se. It would have been obvious to the artisan of ordinary skill to employ balloon, fluid, dispersing fiber, and dye in the combined method of Clarke, Selman et al and Waksman et al since this too will prevent restenosis, and in either case to employ a lenticular element to disperse the light in the method of Spears, since Spears teaches no particular pattern to do so, thus producing a method such as claimed.

Applicant argues that the method of Clarke does not damage the endothelium layer. This argument is not convincing because as widely known in the art, and as specifically disclosed in the specification ultraviolet light such as employed by Clarke is highly absorbed by tissue, thus any endothelium cells present at the surface of blood vessels when they are treated would necessarily be ablated (e.g. destroyed) by the application of radiation thereto. However, in order to further clarify the rejections, the Waksman et al reference, which teaches that both the

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endothelial cells and the smooth muscle cells play a role in restenosis and shows that these structures are similarly damaged by the treatment to prevent restenosis.

With regard to the rejection involving Anderson et al, since Anderson et al specifically teach treating the surface, the rejection is proper as it stands. Applicant argues that the statement that the “intensity of the illumination... is correlated with the extent of photodynamic killing” in Anderson et al would “dissuade” one having ordinary skill from combining the disclosures of Clarke and Anderson et al, however no underlying rationale as to why this teaching would “dissuade” one having ordinary skill is offered. While applicant’s arguments in this regard are noted, they are not convincing as Clarke gives no caution that the intensity or wavelength of the flashlamp cannot or should not be controlled. Since applicant has provided no particular line of reasoning as to why these references are uncombinable, and since the line of reasoning that could be inferred by the examiner is refuted above, these arguments are not convincing.

Regarding the combination of Clarke and Selman et al applicant argues that the two references are directed at different, defined tissues. The examiner respectfully submits that applicant has misinterpreted the Clarke reference. Clarke clearly states that the endothelium of a vessel is interrupted by the plaque (see Column 5, lines 46-48) and that after the intervening plaque is removed the radiation is directed to the muscle cells (see column 5, lines 52-56). Thus the differences in the layers killed is due to the different layers that the radiation is actually delivered to, and thus one having ordinary skill would not hesitate to employ the method of Selman et al in that of Clarke. The examiner also notes that regardless of the foregoing applicant’s arguments are inapplicable to the substitution of a flashlamp in the method of Selman et al both because Clarke gives no indication that the light from the flashlamp cannot or should

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not be controlled and because the wavelengths and intensities for producing the ablation must already be known to the artisan of ordinary skill, since no particular wavelength and/or intensity are disclosed by applicant.

Applicant's arguments filed January 13, 2003 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

Applicant's arguments with respect to claims 14-24 and 33-40 have been considered but are moot in view of the new ground(s) of rejection.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number 703-308-2215.

Shay/DI

March 27, 2003



DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330